

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

HORIZON MEDICINES LLC,

*Plaintiff,*

v.

ALKEM LABORATORIES LTD.,

*Defendant.*

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C.A. No. 1:18-cv-01014-RGA

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Public Version Filed: August 20, 2021

**DECLARATION OF AMIT GHARE IN SUPPORT OF ALKEM'S ANSWERING  
BRIEF IN OPPOSITION TO HORIZON'S EMERGENCY MOTION FOR AN  
INJUNCTION PENDING APPEAL AND A TEMPORARY RESTRAINING ORDER**



I, Amit Ghare, hereby declare and state as follows:

1. I joined Alkem Laboratories Ltd. (“Alkem”) in October 2008. I am the Head of International Business of Alkem, including business in the United States. I relocated to Alkem’s wholly-owned subsidiary in the United States, Ascend Laboratories, LLC, in July 2020. I currently hold the title of President and Chief Executive Officer of Ascend Laboratories, LLC.

2. Alkem is a leading Indian pharmaceutical company with global operations, and is engaged in the development, manufacture and sale of branded generics, generic drugs, active pharmaceutical ingredients and nutraceutical products. Established in 1973 and headquartered in Mumbai, Alkem is ranked the fifth-largest pharmaceutical company in India in terms of domestic sales. Alkem’s global presence spans about fifty (50) international markets, including the United States.

3. Alkem earned nearly \$1.2 billion (USD) in revenue for its fiscal year ending March 31, 2021. Alkem’s most recent quarterly financial results, for the period ending June 30, 2021, report a year-on-year growth of 37.1%.

4. I am responsible for directing and managing Alkem’s U.S. business including marketing and sales efforts, product launches, supply chain management, revenue and profitability and overall operations, including as relevant to Alkem’s generic ibuprofen and famotidine tablets, 800 mg and 26.6 mg, products (“ibuprofen/famotidine ANDA products”). I work directly with Alkem’s pricing group to set the prices for Alkem’s generic products, and to negotiate and bid for supply and sales contracts with Alkem’s customers, which include pharmaceutical chains, wholesalers, generic distributors, mail-orders and others. I have full profit-and-loss, budget and expense responsibility for Alkem’s U.S. business.



5. I have personal knowledge of the facts stated in this Declaration, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.

6. I submit this Declaration in support of Alkem's Answering Brief in Opposition to Plaintiff Horizon Medicines LLC's Emergency Motion for an Injunction Pending Appeal and a Temporary Restraining Order.

**I. Personal Background.**

7. I have over 20 years of pharmaceutical industry sales and marketing experience. During that time, I gained extensive experience dealing with all aspects of the marketing and sale of generic pharmaceutical products.

8. I have been intimately involved with the introduction of new generic drugs into the market. As a result, I understand the significant harms that would be inflicted on Alkem if it is not permitted to continue marketing its ibuprofen/famotidine ANDA products, which the U.S. Food and Drug Administration ("FDA") approved on August 3, 2021. Alkem commercially launched its ibuprofen/famotidine ANDA products on August 3, 2021 (U.S. time), following receipt of that approval and what I understand was the entry of a favorable district court trial decision for Alkem in November 2020. This was a very important generic product launch for Alkem, as explained further below, especially since Alkem's ibuprofen/famotidine ANDA products are the first generic ibuprofen and famotidine tablets products approved by FDA, and Alkem's customers have been anticipating commercial launch of this lower-priced competing generic product.

9. On numerous occasions, I have been involved in evaluating potential launches of a new generic drug. Such analysis typically involves considering standard industry formulas to project the price, market share, net sales and profits that can be expected upon the launch of a new

generic product. The anticipated number of competitors and day of their entry is a critical input underlying such analysis.

10. I have extensive experience with, and knowledge of, the costs generic companies incur prior to launch, including pre-launch manufacturing and supply chain execution and other costs. I am thoroughly familiar with Alkem's financial analysis relating to its ibuprofen/famotidine ANDA products.

## **II. Alkem's Business in the United States.**

11. Alkem is in the business of developing and marketing generic versions of prescription drugs. A generic drug is a version of a brand name drug that is generally sold without a trade name or trademark. The generic drug is bioequivalent and interchangeable to the brand name drug. Typically, generic drugs are priced substantially lower than their brand-name counterparts.

12. The generic drug business is extremely competitive. Generic drug companies compete for the business of a limited number of major customers, which account for a significant percentage of all generic drug purchases in the United States. Once a generic company forms a relationship with one of those major customers with respect to a particular product and launch, it obtains a significant advantage in maintaining that supply relationship going forward. Generic drug companies therefore rely on entering a market as soon as possible after approval of an Abbreviated New Drug Application ("ANDA") to give them the best chance for securing major customers. Early market entry also often means fewer competitors, which provides greater access to customers and generates critical profits that would not otherwise be available as additional competitors enter the market. Margins on generic products with fewer competitors are also significantly higher and thus provide a unique and necessary opportunity to recoup the costs of (i)

developing these products; and (ii) defending patent infringement lawsuits that generic companies bear in order to accelerate the introduction of lower-priced generic products into the market.

13. Generic drug companies that have the opportunity to enter a market early with fewer competitors have a significant advantage in entering into, and maintaining, supply relationships with major customers to the exclusion of generic companies that enter the market later. This is especially true in a market in which no other generic is currently FDA-approved, as relevant here with the ibuprofen and famotidine tablets market. This period of limited competition provides considerable tangible and intangible benefits, many of which are not quantifiable, as discussed herein, such as improved and longer-term customer relationships. Once multiple generics have entered a market, price and market share competition is typically intense, which reduces sales realizations and profit margins substantially. This emphasizes the criticality of an effective launch as soon as possible following FDA approval. The intangible benefits of improved access to key customers, improved goodwill and enduring market share are extremely significant to Alkem and its business strategy. The loss of these benefits can, and often does, cause significant harm to a generic company that is not quantifiable.

### **III. Alkem's Ibuprofen and Famotidine Tablets, 800 mg and 26.6 mg, ANDA.**

14. In order to commercially sell a generic version of a drug product, such as ibuprofen and famotidine tablets, in the United States, Alkem has to undertake a development of its ANDA dossier for submission to FDA. This development process typically takes 18-24 months on an average and is also cost intensive.

15. Alkem filed an ANDA (No. 211890) with FDA seeking regulatory approval to market ibuprofen and famotidine tablets, 800 mg and 26.6 mg in 2018.

16. Alkem spent considerable time and sums developing its generic ibuprofen and famotidine tablet products for eventual sale in the United States, including compiling the information required to obtain approval of its ANDA No. 211890.

17. To date, Alkem has expended millions of dollars (USD) in connection with its efforts to bring its ibuprofen/famotidine ANDA products to the U.S. market, including expenses related to conducting bioequivalency studies, obtaining raw materials for a commercial launch, and litigation.

18. FDA granted tentative approval to ANDA No. 211890 on December 23, 2019, and final approval on August 3, 2021. In issuing this approval, FDA found that Alkem's ibuprofen/famotidine ANDA products are safe and effective for use as prescribed in the approved labeling.

#### **IV. The Ibuprofen and Famotidine Tablets Market.**

19. I understand Horizon Medicines LLC ("Horizon") currently markets and sells DUEXIS®, a prescription drug known by the generic name ibuprofen and famotidine tablets, 800 mg and 26.6 mg. DUEXIS® is a combination of the nonsteroidal anti-inflammatory drug (or NSAID) ibuprofen and the histamine H2-receptor antagonist famotidine. DUEXIS® is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials were defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications.

20. Based upon the available market data, (i) sales (brand) of DUEXIS® totaled nearly \$125.3 million (worldwide) in 2020; and (ii) units (bottles of 90 tabs) sold of DUEXIS® totaled approximately 344,504 during that same period.

21. This market provides a generic entrant with enormous opportunity, particularly as a first and sole entrant, as here, and no other generic is currently approved by FDA. Moreover, as

[REDACTED]

a leader in the generic pharmaceutical industry that is widely recognized for its high-quality products and supply capabilities, Alkem is capable of supplying the entire market.

**V. Alkem Will Suffer Substantial Irreparable Harm if Horizon's Request for an Injunction Pending Appeal Is Granted.**

22. It is my understanding that Horizon is seeking an injunction that would force Alkem to halt sales of its FDA-approved ibuprofen/famotidine ANDA products, and is seeking to have Alkem issue a recall of those products. Alkem would be substantially and irreparably harmed if the Court were to grant Horizon's requested relief.

23. As an initial matter, the harm to Alkem if an injunction issues would be particularly irreparable here because, as noted above, Alkem launched its ibuprofen/famotidine ANDA products on August 3, 2021, following entry of a trial decision in its favor and FDA approval.

24. As I understand it, no other generic version of ibuprofen and famotidine tablets is currently on the market, or FDA-approved at this time (although I understand at least three other ANDAs, owned by Par,<sup>1</sup> Teva and Torrent, respectively, are pending before FDA for a generic ibuprofen and famotidine tablets product). In such circumstance, the potential to gain a substantial market share, together with greater long-term sales and customer relationships, is enormous. For instance, based on my experience in the pharmaceutical industry, generic entrants could obtain a substantial percentage of the market share of a product. In this particular case, [REDACTED]

[REDACTED] Given the size of this market and the fact that there are no other generic players on the market, this is a critical opportunity for Alkem that will be forever lost if it is enjoined during an appeal. In fact, the window for this opportunity would

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<sup>1</sup> I understand that as part of a License Agreement entered in or around August 2013, Horizon granted Par the non-exclusive right to market a generic ibuprofen and famotidine product beginning January 1, 2023, or earlier under certain circumstances.

[REDACTED]

likely close if Alkem is enjoined, since other competitors may be ready to enter the market upon FDA approval, or Horizon could launch an authorized generic—under any of these scenarios, Alkem’s “first and sole mover advantage” here would be lost.

25. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

26. [REDACTED]

[REDACTED]

On top of that, Alkem’s generic products have certain expiration-dating/shelf life. If those products cannot be sold now, Alkem may not be able to sell those products at all in the future if they do not have sufficient remaining shelf-life (customers generally demand greater than 12 months of remaining expiration-dating/shelf life).

27. Generally speaking, Alkem’s investment in its remaining inventory is in serious jeopardy and is likely to be either lost altogether or sold at an extremely low price, if this Court grants the injunctive relief requested by Horizon.

28. In addition to these tangible harms, there are considerable intangible harms that are not quantifiable. Alkem’s long-term relationships with its customers will suffer greatly if Alkem is not able to fulfill its customers’ needs. To this end, it is public knowledge that FDA approved Alkem’s ibuprofen/famotidine ANDA products for sale in the U.S. market as of August 3, 2021; that Alkem obtained a favorable trial ruling on November 30, 2020; and that Alkem commercially

launched its ibuprofen/famotidine ANDA products on August 3, 2021, following FDA approval. Alkem's customers are acutely aware of these facts and expect that Alkem will continue to provide them with a competing lower-priced generic product now.

29. In light of industry expectations that Alkem will make these products available to its customers, if Alkem is prevented from marketing even temporarily, its customers will lose faith in its ability to fill their orders later in time. Indeed, that is the primary purpose of Alkem's generic business, namely, to bring competing generic products to market as soon as possible, and especially when, as here, Alkem has secured a favorable trial ruling. Entry of an injunction could also negatively impact Alkem's sales in other areas, particularly in view of reputational damage. This harm will only be further exacerbated if Alkem is forced to withdraw or recall its ibuprofen/famotidine ANDA products already launched to these customers, as I understand Horizon has requested.

30. Alkem also committed significant resources and investments in preparing its ibuprofen/famotidine ANDA products for the U.S. market. These resources and investments could have been used for other purposes, for example, developing new products. The resources required for the preparation of the ANDA, and the launch of Alkem's ibuprofen/famotidine ANDA products, are substantial. There will be no way to compensate Alkem for the use of these resources should Alkem be forced to forego marketing its products.

31. Further, the damage to Alkem would be exacerbated by the fact that Alkem, in addition to the costs already discussed, has invested considerable resources to litigate the merits of the litigation before this Court.

## **VI. An Appropriate Bond.**

32. If the Court grants Horizon's injunction pending appeal, it is imperative that Horizon be required to post a bond in an amount adequate to protect Alkem during the entire

injunction period, no matter how long it may last. I am in a position to provide the Court with information sufficient to determine an appropriate bond amount in the event the Court decides to enter an injunction (of any length).

## **VII. Alkem's Ability to Pay Damages.**

33. Finally, as I understand it, Alkem would be able to pay any damages award that might occur in the event Horizon ultimately prevails on the merits of its appeal.

34. As discussed above, Alkem is currently ranked the fifth largest pharmaceutical company in India in terms of domestic sales. Alkem generated nearly \$1.2 billion (USD) (= 91.0 billion Indian Rupees (INR) / 74.2 INR per USD) in revenue during FY-21 (12 months ending March 31, 2021).<sup>2</sup>

35. Further, as disclosed on Alkem's Consolidated Balance Sheet (Ex. 1 at 164), Alkem has approximately:

- \$268.7 million (USD) in cash and bank balances (= [1.74 billion INR (cash balance) + 18.2 billion INR (bank balances, i.e., bank deposits with less than 12 months maturity)] / 74.2);
- \$217.0 million (USD) in receivables (= 16.1 billion INR / 74.2); and
- \$1.5 billion (USD) in company assets overall (= 115.2 billion INR / 74.2, includes inventories, financial assets, non-current assets, and other current assets).

36. Alkem has experienced another successful financial quarter of approximately \$376 million (USD) in revenue (= 27.8 billion INR / 73.8) and \$75.4 million (USD) in operating profit (= 5.561 billion INR / 73.8) from April to June 2021. (See Ex. 2 hereto, Consolidated Financials).

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37. The foregoing facts are true and correct as I verify and believe.

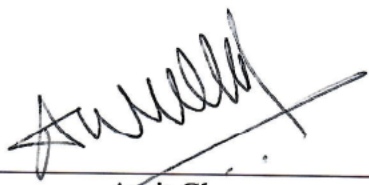
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<sup>2</sup> The conversion rates used herein are based on the data provided by Federal Reserve Economic Data, India / U.S. Foreign Exchange Rate (EXINUS) (<https://fred.stlouisfed.org/series/EXINUS>) for the relevant timeframe.



I declare under penalty of perjury, under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing is true and correct.

Dated: August 12, 2021.

  
A handwritten signature in black ink, appearing to read "Amit Ghare", is written over a horizontal line. The signature is stylized with a large initial 'A' and a long horizontal stroke.